REMARKS

The present document is submitted in reply to the Office Action dated April 14, 2008 ('Office Action").

Claims 22-27, 29-57, 59, and 62-67 are currently pending, among which, claims 22-26 and 30-57 have been withdrawn from consideration.

Applicants have amended claim 67 to more particularly point out the subject matter of their invention and amended the specification to promote clarity. These amendments have not introduced new matter. Finally, Applicants have cancelled claim 65.

Upon entry of the present amendments, claims 27, 29, 59, 62-64, 66, and 67 will be under examination. Applicants respectfully request that the Examiner reconsider this application in view of the following remarks.

Objections to the Specification

The Examiner objects to the specification for lack of clarity on six grounds. See the Office Action, page 3. Applicants address each ground below.

(1) The phrase "a varying experimental reagent," recited at page 2, line 9, page 5, lines 24-25, and page 6, line 27, is deemed vague on the ground that one cannot subject "a reagent" to "varying." Applicants have replaced this phrase with "an experimental reagent."

(2) The phrase "collect a large number of blood sample denatured lipoprotein," recited at page 3, lines 15-16, is deemed not clear. Applicants have rewritten it into "collect a large number of denatured lipoprotein from sera samples."

(3) The Examiner asserts that it is unclear as to what the term "reconstructive lipoprotein" recited at page 4, line 17 refers to. Applicants would like to bring to the Examiner's attention that the specification describes "reconstructive lipoprotein" by referencing US Patent 5,652,339.[1] See page 4, lines 18-19. This US patent, titled "Method of Producing Reconstituted lipoproteins," teaches what a reconstituted

[1] Applicants would like to point out an inadvertent error in the specification. More specifically, "US Patent 5,652,399" recited at page 4, line 19 should read "US Patent 5,652,339." Applicants have amended the specification to correct this error.

lipoprotein (a synonym of reconstructive lipoprotein) is, i.e., a lipoprotein formed of isolated or recombinant apolipoproteins and suitable lipids. See column 1, lines 32-34; column 4, lines 60-64. In view of this teaching, a skilled person in the art would readily know what the term "reconstructive lipoprotein" refers to.

(4) The phrase "incorporating into blood plasmlipropotein," recited at page 5, line 7, is deemed unclear with respect to the identity of "plasmlipropotein." Applicants have amended the phrase at issue to make it clear that "plasmlipropotein" refers to lipoproteins in blood plasma.

(5) The sentence bridging pages 5-6 is deemed incomprehensible for containing too many commas and semicolons. Applicants have rewritten this single sentence into a paragraph that contains several independent sentences. The meaning of this amended paragraph is believed to be self-explanatory.

(6) The phrase "severally containing lipoprotein," recited at page 6, line 1, is deemed unclear. Applicants have deleted this phrase.

It is respectfully submitted that all of the above grounds have been removed.

Rejection under 35 U.S.C. § 112, Second Paragraph

Claim 67 is rejected for indefiniteness on two grounds, which are addressed below.

First, the Examiner states that, while the preamble of claim 67 reads "a method for producing a stabilized denatured **oxidized** lipoprotein standard," the steps recited therein do not reflect how an **oxidized** lipoprotein standard is obtained. Applicants have deleted the word "**oxidized**" from the preamble.

Second, the Examiner asserts that the purpose of reciting a determining step in claim 67 is not clear. For the sole purpose of accelerating prosecution, Applicants have removed this step.

Rejection under 35 U.S.C. § 103

Claims 27, 29, 59, 62-67 are rejected for obviousness over Kimura et al., PTO 07-6676, English translation of JP 09-2881064 ("Kimura"), in view of Proksch et al. US

Patent 4,216,117 ("Proksch"). Applicants respectfully disagree. Note that claim 65 has been cancelled.

Independent claim 27 will be discussed first. This claim covers a method for **producing** a stabilized denatured lipoprotein standard, including (a) **freezing** a lipoprotein-containing solution to produce a frozen solution; (b) **melting** the frozen solution to produce a melted solution containing denatured lipoprotein; (c) mixing the melted solution with a stabilizing agent to form a solution; and (d) freeze-drying the solution to produce the stabilized lipoprotein standard, in power form.

Kimura teaches a method for **quantifying** human lipoprotein oxide with a particular antibody. See paragraphs [0012] and [0016]. It also teaches a standard substance to be used in the just-mentioned **quantification** method, i.e., a compound obtained from oxidation of a phospholipid, and incorporation of the standard substance into plasma proteins to produce a denatured lipoprotein standard. See paragraphs [0020], and [0054-0056]. Clearly, this reference does not teach or suggest the method of claim 27 covering **production** of a stabilized denatured lipoprotein standard including the steps described in the preceding paragraph (e.g., the **freezing** and **melting** steps).

Proksch teaches a lipoprotein diluent useful in preparing a standard material. See Abstract. According to Proksch, the lipoprotein diluent is prepared by obtaining a lipoprotein fraction from plasma or serum and combining the lipoprotein fraction with water, carbonate, or other dilute salt solutions, and preferably also with a preservative. See column 5, lines 40-55. Thus, **the Proksch method** for producing the lipoprotein diluent **does not include**, among others, **any freezing or melting step**, as those recited in claim 27.

Proksch further teaches a method of making a standard material by mixing the lipoprotein diluent described in the preceding paragraph with a lyophilized serum base. See columns 5-6, bridging paragraph. The standard material thus obtained can be lyophilized for various purposes. See column 6, lines 24-30. Taken together, **the Proksch method for producing the standard material** includes (1) the obtaining step and the combining step for making the dilute (see the preceding paragraph), and (2) the

just-mentioned mixing step and freeze-drying (lyophilizing) step. In other words, unlike claim 27, **this method also does not include any freezing and melting steps**.

In sum, for the reasons set forth above, neither Kimura nor Proksch suggests a method that includes a **freezing step** and a **melting step** for preparing a denatured lipoprotein standard, as the method of claim 27. Thus, these two references, either taken alone or in combination, do not render claim 27 obvious. Nor do they render obvious claims 29, 59, and 62-64, all of which depend from claim 27.

Turning to claims 66 and 67, the other two independent claims, Applicants would like to point out that both claims recite the same steps as those recited in claim 27, including the **freezing** and **melting steps**. For the same reasons, these two claims are also not obvious in view of Kimura and Proksch.

For a complete record, Applicants now address the Examiner's ground for rejection.

The Examiner asserts that Proksch teaches the **freezing** and **melting** steps required by the rejected claims. See the Office Action, page 5, last paragraph. Applicants respectfully disagree and have quoted the exact text of the passage relied on by the Examiner, i.e., column 3, lines 57-59:

> "For the purpose herein, **the term** 'turbidity-potential lipoproteins' is **intended to mean** those lipoproteins which are associated with the turbidity produced in serum which is **frozen and thawed** or which is lyophilized and reconstituted with an aqueous media;" emphases added.

Applicants would like to bring to the Examiner's attention that the above-quoted passage defines the term "turbidity-potential lipoprotein," i.e., lipoproteins that cause turbidity in certain situations. According to this definition, "**frozen and thawed** (melted)" is merely a situation in which turbidity-potential lipoproteins cause turbidity; this phrase does not refer to any step required by the Proksch method for making a lipoprotein diluent or the Proksch method for making a standard material. In other words, contrary to the Examiner's assertion, the above-quoted passage does not suggest that any of the two Proksch methods include a **freezing** step and a **melting** step.

In view of the foregoing remarks, Applicants respectfully request withdraw this rejection.

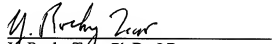
CONCLUSION

It is believed that all of the pending claims have been addressed. However, the absence of a reply to a specific rejection, issue or comment does not signify agreement with or concession of that rejection, issue or comment. In addition, because the arguments made above may not be exhaustive, there may be reasons for patentability of any or all pending claims (or other claims) that have not been expressed. Finally, nothing in this paper should be construed as an intent to concede any issue with regard to any claim, except as specifically stated in this paper, and the amendment of any claim does not necessarily signify concession of unpatentability of the claim prior to its amendment.

No fee is believed to be due. Please apply any charges to Deposit Account No. 50-4189, referencing Attorney Docket No. 56501-002001.

Respectfully submitted,

Date: 7-14-08



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